

REMARKS

As an initial matter, Applicant wishes to thank the Examiner for acknowledging that the amendment to Claim 1 makes the elected claims 1, 3, 4, 7, 10, 12-17, and 30 allowable over the prior art cited in the Office Action having a mailing date of April 5, 2006.

Claims 1, 3-10, 12-17, 23-25, and 30 are pending in this Application. Claims 1, 8, 15, and 25 are amended, among others, to correct grammatical and/or spelling errors. New Claims 31 and 32 have been added. Upon entry of this Amendment and Response, Claims 1, 3-10, 12-17, 23-25, 30, 31, and 32 will be pending in this Application with Claims 5, 6, 8, 9, and 23-25 having been withdrawn from consideration by the Examiner.

Claim Objections

Claim 1 is objected to because of the conjunction “or” is repeated in the terminal “wherein” clause.

The first occurrence of “or” in this clause is deleted as suggested by the Examiner, thereby obviating this objection.

Double Patenting

Claims 1, 3, 4, 7, 10, 12-17, and 30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-3, 6-11, 15, and 34-36 of copending Application No. 10/427,929.

Claims 1, 3, 4, 7, 10, 12-17, and 30 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 25, 28, and 29 of copending Application No. 10/669,251.

Applicant respectfully requests that this issue be deferred until allowable subject matter is indicated.

Rejection under 35 U.S.C. §112, first paragraph

Claims 1, 3, 4, 7, 10, 12-17, and 30 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. In particular, the Office Action alleges that “The specification fails to exemplify or describe the ... methods ... wherein a serine protease inhibitor inhibits serine proteases generally, metalloproteases, or other polypeptides in

inhibiting apoptosis, apart from the inhibition of the proteolytic activity of a caspase, a granzyme, or a cathepsin. ... Neither the claims nor the specification describe any protease other than caspases, granzymes, and cathepsins that mediates apoptosis and is inhibited by a serine protease inhibitor....” See page 4 of the Office Action.

On one hand it appears the Office Action is acknowledging that (1) the specification shows serine protease inhibitors inhibit serine proteases such as caspases, granzymes and cathepsins, and (2) these serine proteases mediate apoptosis. (“Neither the claims nor the specification describe any protease **other than** caspases, granzymes, and cathepsins **that mediates apoptosis and is inhibited by a serine protease inhibitor**...”). (Emphasis added). Page 4 of the Office Action. On the other hand, the Office Action appears to be alleging that the specification fails to exemplify or describe a serine protease inhibitor inhibiting apoptosis. (“The specification fails to exemplify or describe the ... methods ... wherein a serine protease inhibitor ... inhibiting apoptosis. ...”). Page 4 of the Office Action.

Since the Office Action appears to acknowledge that inhibiting serine protease inhibitors such as caspase, granzymes, and cathepsins inhibit apoptosis, it is unclear what the basis is for this nonenablement rejection. Accordingly, Applicant respectfully requests clarification of this apparent inconsistency in the Office Action.

The Office Action also alleges that “the specification...fails to disclose that an α_1 -antitrypsin inhibitor is delivered to the cytosolic or nuclear compartments of any mammalian cell that may undergo apoptosis in tissues wherein the medical conditions recited in claim 1 transpire, e.g., neurons, epithelial cells, muscle cells, or connective tissue cells.” *Id.* Furthermore, the Office Action alleges that:

Claims 1, 3, 4, 7, 10, 12-17, and 30 contemplate the inhibition of apoptosis in a subject by the elected protease inhibitor which is a polypeptide.... The specification does not teach, and the prior art of record herein does not disclose, how to introduce an α_1 -antitrypsin inhibitor within the cytosolic and nuclear compartments of nervous, muscular, epithelial, or connective tissue cells....”

Id. at page 5.

It appears that the Office Action is rejecting the claims as allegedly being nonenabling because “The specification does not teach...how to introduce [a polypeptide] within the cytosolic and nuclear compartments of nervous, muscular, epithelial, or connective tissue cells....” See pages 4 and 5, respectively, of the Office Action.

When rejecting a claim under the enablement requirement of §112, the Patent Office bears the “initial burden of setting forth a reasonable explanation as to why...the scope of protection provided by [the] claim is not adequately enabled by the description of the invention provided in the specification.” *In re Wright*, 27 U.S.P.Q.2d. 1510, 1513 (Fed. Cir. 1993). To object to a specification on the grounds that the disclosure is not enabling with respect to the scope of a claim sought to be patented, the Examiner must provide evidence or technical reasoning substantiating those doubts. *Id.*; and M.P.E.P. §2164.04. Without a reason to doubt the truth of the statements made in the patent application, the application must be considered enabling. *In re Wright*, 27 U.S.P.Q. 2d at 1513; *In re Marzocchi*, 169 U.S.P.Q. at 369.

The Office Action does not provide any evidence or technical reasoning substantiating this alleged nonenablement. The Office Action simply concludes that “The specification does not teach...how to introduce [a polypeptide] within the cytosolic and nuclear compartments of nervous, muscular, epithelial, or connective tissue cells....” See page 5 of the Office Action. The Examiner fails to specifically identify why a serine protease inhibitor can not be introduced within the cytosolic and nuclear compartments of nervous, muscular, epithelial, or connective tissue cells. Since the Office Action does show any evidence supporting the alleged nonenablement, the Examiner has not met this initial burden of proof, and therefore the nonenablement rejection is improper.

In the event the Examiner maintains the nonenablement rejection, the following arguments clearly show that the specification is enabling. First of all, it is submitted that the Examiner’s apparent interpretation that all serine protease inhibitors are polypeptides is improper. There is nothing in the specification that limits serine protease inhibitors to only polypeptides. Secondly, in the Office Action having a mailing date of April 5, 2006, the Examiner cited various references as allegedly rendering the previous Claims obvious. In particular, in that Office Action, the Examiner stated that cited reference “teaches that the administration of human α_1 -antitrypsin inhibitor in treating an autoimmune disease....” See page 4 of the Office Action dated April 5, 2006. Accordingly, in contrast to the Examiner’s current, and apparently contradictory, position one skilled in the art clearly has sufficient skill and knowledge to practice the present invention as claimed without undue experimentation.

In view of the above, it is respectfully submitted that the rejection under 35 U.S.C. §112, first paragraph, is improper and should be withdrawn.

Rejection under 35 U.S.C. §112, second paragraph

Claims 1, 3, 4, 7, 10, 12-17, and 30 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Office Action alleges “the recitation ‘at least one of Alzheimer’s disease ... Downs Syndrome ... or neurodegenerative disease’ combines terms describing specific neurodegenerative medical conditions ... with ... [a term] that describes multiple medical conditions.”

Claim 1 has been amended as suggested by the Examiner by removing the terms “Alzheimer’s disease” and “Downs Syndrome” from Claim 1 in favor of introducing them in a separate dependent claim.

Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

CONCLUSION

In view of the foregoing, Applicants submit that all claims now pending in this Application are in condition for allowance. Therefore, an early Office Action to that effect is earnestly solicited. If the Examiner believes a telephone conference would aid in the prosecution of this case in any way, please call the undersigned at (303) 955-8103.

Respectfully submitted,

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